

REMARKS

Claims 1-12 are pending in the present application.

The rejection of Claims 1-2 under 35 U.S.C. §102(b) over Sloma et al is obviated in part by amendment and traversed in part.

The rejection over Sloma et al as anticipating the claims is without merit over Claim 1, but appears to be proper over original Claim 2. In making this rejection, the Examiner alleges that Sloma et al disclose a sequence with 95% homology to SEQ ID NO: 1.

However, the sequence of Sloma et al does not meet the limitations of Claim 1, which requires that the sequence be SEQ ID NO: 1, with the possible specifically recited mutations. As such, Claim 1 cannot be anticipated since all the elements of the claim is not disclosed by Sloma et al.

Turning to Claim 2, the Examiner has held that species (c) is met by the Sloma et al disclosure. In making this assertion, the Examiner appears to recognize that the elected species (species (a)) is free from the art of record and, therefore, has expanded her search to other species for which Applicants thank the Examiner. However, the claim as originally presented (i.e., 80% homology) is held to read on the art of record. To this end, Applicants have amended Claim 2 to limit the scope of homologs to those having at least 95% homology to SEQ ID NO: 1. It should be noted that the actual sequence disclosed by Sloma et al as reading on the claimed invention (SEQ ID NO: 42) is actually only 94.6% homologous, not 95% as alleged by the Examiner (see sequence alignment attached to the Office Action mailed on April 19, 2006). Therefore, Sloma et al fails to anticipate the invention of amended Claim 2.

Applicants request withdrawal of this ground of rejection.

The rejections of Claim 2 under 35 U.S.C. §112, first paragraph (written description and enablement), are obviated by amendment.

The Examiner has rejected Claim 2 based on the breadth of the permissible homologs of the claimed amino acid sequence of SEQ ID NO: 1. Indeed, it is the current trend in U.S. patent practice to narrow the permissible scope of homologs. However, Applicants direct the Examiner's attention to a recent decision by the U.S. PTO's Board of Patent Appeals and Interferences (*Ex parte Bandman*, copy **enclosed herewith**) that held that claims to polypeptides and/or polynucleotides sequences that are at least 95% identity to the disclosed sequence are adequately described and enabled when the specification describes the nucleotide and amino acid sequences. As in *Ex parte Bandman*, the present application fully discloses the polynucleotide of SEQ ID NO: 2, which includes the polypeptide of SEQ ID NO: 1, and provides support for homologs of at least 95% (see page 8). As such, the specification adequately meets the current standard of the Office and should be entitled to sequences that are at least 95% homologous to SEQ ID NO: 1. Indeed, the Examiner recognizes that this scope is enabled in her comments relating to the enablement rejection (see page 9 of the Office Action mailed April 19, 2006).

Withdrawal of these grounds of rejection is requested.

The rejection of Claim 2 under 35 U.S.C. §112, second paragraph, is respectfully traversed.

The Examiner has objected to the use of the term "homology" in Claim 2 as being indefinite, alleging that "homology refers to ancestral or evolutionary linkage, not percent sequence identity that is calculated by a mathematical algorithm." This allegation is not

supported by any references or further explanation. Applicants further submit that the term “homology” has been widely recognized by the Office to be appropriate in claims to polynucleotide and amino acid sequences. In fact, a key word search of the USPTO Patent Full-Text and Image Database from 1976 to present using the search terms “protein” and “homology” as claim terms resulted in 381 patents. Five representative examples that have the same contextual usage of the term “homology” as the present application are: US 6,995,250, US 7,026,151, US 7,029,860, US 7,029,896, and US 7,049,860.

Moreover, Applicants submit that “homology” is defined on page 8 of the specification with reference to an algorithm for determining the same. Applicants wish to remind the Examiner that: “Applicants are their own lexicographer” (MPEP §2173.01). MPEP §2173.01 also states that Applicants “can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art.” Further, definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made (MPEP §2173.02).

Applicants submit that page 8 of the specification evidences the content of the application disclosure, while the aforementioned US patents evidence the teachings in the art and the interpretation of the skilled artisan. As such, Applicants submit that the term “homology” in Claim 2 is not indefinite.

In view of the foregoing, withdrawal of this ground of rejection is requested.

The rejection of Claims 1-2 under 35 U.S.C. §101 is believed to be obviated by amendment.

The Examiner has held that the original "alkaline protease" claims read on products of nature. As such, the Examiner has recommend that Applicants add the term "isolated" to the preamble of these claims. Consistent with the Examiner suggestion, the claims have been amended accordingly.

Withdrawal of this ground of rejection is requested.

The objection to Claim 1 (and Claim 2) is believed to be obviated by amendment.

The Examiner has objected to the language of Claim 1 (and Claim 2). In addition, the Examiner has proposed an amendment that she believes would overcome this ground of objection. At least as far as Claim 1 is concerned, this amendment appears to be acceptable. However, with respect to Claim 2, it is important that the phrase "or at positions corresponding to these positions" be maintained. As the skilled artisan would readily appreciate, within the scope of 95% homology to SEQ ID NO: 1 there may not be a one-to-one positional alignment (for example, residue 15 in the homologous polypeptide may not be residue 15 in SEQ ID NO: 1 and when the sequences are aligned it is determined that residue 17 in the homologous polypeptide "corresponds" to residue 15 in SEQ ID NO: 1).

In view of the foregoing, Applicants request withdrawal of this ground of objection.

The objections to the specification and Abstract are believed to have been obviated by amendment.

The Examiner has objected to the specification for several reasons of formalities. Specifically, the Examiner has requested that Applicants: (a) correct a typographical error on

page 16, line 7, (b) expand the Brief Description of the Drawings, (c) add the cross-reference to related applications, and (d) capitalize the tradenames that appear in the specification and add the corresponding generic terminology. The Abstract has also been objected to.

Applicants have made the appropriate amendments to address these criticisms. As such, withdrawal of these grounds of objection is requested.

Accordingly, Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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